

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

<p>IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION</p>	
<p>THIS DOCUMENT RELATES TO:</p> <p><i>The City of New York v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 04-CV-06054</p> <p><i>County of Albany v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0425</p> <p><i>County of Allegany v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0236</p> <p><i>County of Broome v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0456</p> <p><i>County of Cattaraugus v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0256</p> <p><i>County of Cayuga v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0423</p> <p><i>County of Chautauqua v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0214</p> <p><i>County of Chemung v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-6744</p> <p><i>County of Chenango v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0354</p> <p><i>County of Columbia v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0867</p> <p><i>County of Cortland v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0881</p> <p><i>County of Dutchess v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 05-CV-6458</p> <p><i>County of Essex v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0878</p> <p><i>County of Fulton v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0519</p>	<p>MDL NO. 1456 Civil Action No. 01-12257-PBS</p> <p>Judge Patti B. Saris</p> <p>PLAINTIFFS' OPPOSITION TO THE MYLAN DEFENDANTS' INDIVIDUAL MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS</p>

County of Genesee v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-00267

County of Greene v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0474

County of Herkimer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00415

County of Jefferson v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0715

County of Lewis v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0839

County of Madison v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00714

County of Monroe v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6148

County of Nassau v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 04-CV-05126

County of Niagara v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06296

County of Oneida v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0489

County of Onondaga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0088

County of Ontario v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6373

County of Orleans v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6371

County of Putnam v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 05-CV-04740

County of Rensselaer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00422

County of Rockland v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-7055

County of Schuyler v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6387

County of Seneca v. Abbott Laboratories, Inc., et al.

W.D.N.Y. Case No. 05-CV-6370

County of St. Lawrence v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0479

County of Saratoga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0478

County of Steuben v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6223

County of Suffolk v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 03-CV-12257

County of Tompkins v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0397

County of Ulster v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 06-CV-0123

County of Warren v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0468

County of Washington v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0408

County of Wayne v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06138

County of Westchester v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-6178

County of Wyoming v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6379

County of Yates v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06172

INTRODUCTION

Defendants Mylan Laboratories, Inc., Mylan Pharmaceuticals, Inc., and UDL Laboratories (collectively “Mylan”) assert in their motion to dismiss (the “MTD”) that plaintiffs have failed to plead their AWP and Best Price claims in accordance with Fed. R. Civ. P. 9(b). Mylan further contends that spreads between published AWPs and published WACs do not give rise to a claim for fraud. Finally, despite the Court’s repeated statements that evidence of government investigations is relevant,¹ Mylan claims that this evidence is irrelevant and also fails to satisfy Rule 9(b).

Mylan arguments are incorrect. In piecemeal fashion, Mylan claims the pleadings do not satisfy Fed. R. Civ. P. 9(b). The Complaint, however, properly should be examined in its entirety.² Whether individual portions may or may not—in and of themselves—satisfy Rule 9(b) is irrelevant. Second, Mylan entirely disregards the rulings of this Court on Rule 9(b)’s requirements. Plaintiffs have satisfied this Court’s particularity threshold.

ARGUMENT

I. The Consolidated Complaint Adequately Alleges How Mylan’s Price Inflation Schemes Damages Medicaid And Satisfies Fed. R. Civ. P. 9(b)

In its prior opinions, the Court ruled Rule 9(b)’s is satisfied where plaintiffs provide:

- 1) A spread which [plaintiff possesses] a good-faith basis to calculate³ or, alternatively;

¹ See *In re Pharm. Indus. Average Wholesale Price Litig.*, 307 F.Supp.2d 196, 208, 209 (D. Mass. 2004) (“*Pharm III*”); *In re Pharm. Indus. Average Wholesale Price Litig.* No. 01-12257 2004 WL 2387125 at *2 (D. Mass., Oct. 26, 2004) (“*Suffolk IP*”); *In re Pharm. Indus. Average Wholesale Price Litig.* 263 F.Supp.2d 172, 178 (D.Mass. 2003).

² Mylan ignores major portions of the Counties pleadings in its Consolidated Complaint (“CC”) that apply to Mylan. Plaintiffs’ allegations applicable to all defendants are contained in ¶¶ 1-179, pages 1-58. Of these 100+ paragraphs of allegations, Mylan cites only three when summarizing plaintiffs’ allegations.

³ In *Suffolk II*, 2004 WL 2387125, at *2 (D.Mass. 2004), the Court held that in the absence of allegations particularizing the circumstances surrounding the price reporting, Suffolk could satisfy 9(b) by alleging a spread which for which it has “a good-faith basis”. See *id.*, (“[t]he so-called “Suffolk 13” ...insist that the allegations concerning the spread are not particular enough because ... there are no ...allegations (e.g., government investigations or the company’s own internal documents) to support a claim of fraudulent pricing.... If there is a good faith basis for calculating a spread, the Court will deny the motion to dismiss”).

- 2) A detailed overview of the fraudulent scheme that fits the “paradigm described in the complaint” (*In re Pharmaceutical Indust. Average Wholesale Price Litig.*, 307 F.Supp.2d 196, 210 (D.Mass.,2004)(“*Pharm III*”)); and
- 3) “[W]ith respect to each defendant, 1) the specific drug or drugs that were purchased from defendant, 2) the allegedly fraudulent AWP for each drug and 3) the name of the specific plaintiffs that purchased the drug.” *Id.* at 208.

The Counties satisfy these requirements. The CC pleads the applicable reimbursement scheme and proffers allegations of defendants’ fraudulent conduct. It details how defendants’ (Mylan included) false price reporting influenced this reimbursement scheme by causing inflated AWP’s and FULs to improperly and fraudulently increase the counties’ reimbursement payments. *See* CC at ¶ 9, 12, 85-87, 122-136. The CC supplements these general allegations with particular details of Mylan’s fraudulent conduct (*see* CC at ¶¶ 608-622) and details the applicable AWP and the spreads between the AWP and Mylan’s actual widely available market prices. *See* Exhibits A & B to CC; *see also* Exhibit A to Plaintiffs’ Opposition to Defendants Consolidated Motion to Dismiss (“Cons. Opp.”).

Mylan first says the CC fails meet Rule 9(b)’s requirements because it fails to “state, drug-by-drug, the allegedly false representations” and “cover[s] prices for selected drugs only for the year 2000.” Mylan MTD at 1-2. The Court squarely held that Counties are not required to plead each product specific and time-specific allegation. *See Pharm III*, 307 F.Supp. at 208 citing *U.S. ex rel. Franklin v. Parke-Davis*, 147 F.Supp.2d 39, 49 (D.Mass.2001) (Saris, J.) (“[W]here the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible”). Plaintiffs have properly provided examples of Mylan’s fraudulent pricing only from the year 2000. Should the Court require such detail for every year at issue in this case, plaintiffs seek leave to file an amendment.

Mylan next argues that with respect to the Mylan defendants, plaintiffs merely claim that AWP is greater than market prices and fail to plead reliance on Mylan prices. MTD at 2. This is

incorrect. Plaintiffs have pled 1) fraudulent conduct (reporting false and inflated wholesale price information); 2) the causal connection (by showing how the applicable reimbursement formulas were inflated by the fraud); and 3) reliance (by showing the money paid by counties on the basis of these inflated reimbursements – CC at ¶¶ 609-611, *passim*).

Plaintiffs further provide each Mylan NDC at issue, its fraudulent AWP, and its purchase by the Counties. *See* CC Exhibit A, pgs. 52 to 58. Finally the plaintiffs set forth those NDCs for which the counties' investigation had already shown Mylan's pricing to be fraudulently misleading by showing those drugs whose AWP's exceeded transaction prices by greater than 40% in 2000. *See* Exhibit B- 22; *see also* CC at ¶¶ 124-127. These allegations adequately particularize Mylan's fraud.

Mylan contends the CC does not allege that there was a spread between the FUL for any Mylan drug and the drug's generally available market price, much less that any spread, if it existed, was fraudulent. *See id.* at 3. But the Counties plead that for brand name drugs and for multi-source drugs without FULs, reimbursements are based on AWP. *See* CC at ¶ 86-88. Multi-source drugs with FULs are reimbursed based on the FUL's, which in turn are based on the price of the "least costly therapeutic equivalent". *Id.* The CC further alleges that Mylan's false price reporting of wholesale price data (false because they fail to report their lowest prices) causes the FUL to be inflated and leads to plaintiffs overpaying as a result of an inflated FUL. *See id.* at 86. In short, the pleadings allege which products were reimbursed based on AWP or FUL, and that even where reimbursed on FUL, defendants' manipulation of such results in Medicaid overcharges. Plaintiffs thus allege a spread between the FUL and any available market price and fail to allege that the spread is fraudulent.

Mylan also contends that spreads between AWP and WACs provide no specificity as to whether the Counties reimbursed on the basis of those reported prices, and the simultaneous publishing makes a fraud claim impossible. *See* Mylan MTD at 4. But plaintiffs' case against Mylan is not based on the spread between AWP and WAC unless that spread exceeds the accepted 1-1.25%. *See* CC ¶¶ 7-8. Plaintiffs' case, as Mylan knows full well, is based on the fact that Mylan reported false pricing information that resulted in false AWP and FULS and overcharges to Medicaid. *See* CC at ¶¶ 9, 12, 85-87, 122-136.

II. THE ALLEGATIONS REGARDING MULTI-SOURCE DRUGS REIMBURSEMENT SATISFY 9(B)

As discussed above and detailed in the opposition to the Sandoz motion, plaintiffs' allegations are sufficiently particular for those Mylan drugs reimbursed at the FUL. The CC generally alleges fraudulent price information, which leads to falsely inflated FULs, which, in turn, leads to Medicaid overcharges. *See* CC at ¶¶ 9, 12, 85-87, 122-136, and Exhibits A&B thereto; *see also* Exhibit A to Cons. Opp. The CC alleges that Mylan knew and took advantage of this fact in order to increase market share and to enrich itself directly. *See id.*

By signing on to the Sandoz motion, Mylan has made the factual claim that its multi-source drugs are fully sealed off from any claims of AWP fraudulent price inflation. Sandoz cites to several multi-source drugs to show their insularity from AWP. But three of the drugs, Albuterol Sulfate 2 mg, Desipramine HCL 50mg and Perphenazine 8mg Tablet Oral 100 were only temporarily subject to the FUL, and then returned to an AWP-reimbursement format. *See* opposition to Sandoz' motion at 4-5.

And Mylan's manipulation of its pricing for Albuterol Sulfate 2 mg tablet also bears mention. As stated in the Sandoz MTD, this drug was on the FUL list only until December of 2002. Publicly available materials from First Data Bank make clear that most defendants (spread

marketing aside) did not increase their Albuterol Sulfate 2mg AWP's after 1994. But Mylan—unlike other defendant manufacturers of Albuterol Sulfate 2mg—continued raising its AWP throughout the period when the drug was on the FUL list, causing it to have one of the highest spreads of any competitor when the drug eventually came off FUL in December 2002. Specifically, during the time that Mylan's Albuterol Sulfate 2mg was on FUL, Mylan manufactured 3 NDCs for this drug, NDCs# 00378025501, 00378025505 and 51079065720. Mylan raised its AWP's to \$0.3086, \$0.3114 and \$0.3207 respectively when the FUL for these NDCs was just \$0.047. The fact is that Mylan's inflated Albuterol Sulfate 2mg tablet AWP's directly caused Medicaid to pay spreads of 400-600% more for these NDCs once Albuterol Sulfate 2mg tablet came off the FUL list.⁴

While the foregoing analysis is not expressly detailed in the CC, should the Court require such analysis for every Mylan drug subject to the FUL, for every year from 1994-present, plaintiffs can provide such given their recent acquisition of transaction level price data. Cicala Affidavit at ¶25-26. In this case, plaintiffs would request leave of court to promptly amend their complaint and/or the exhibits thereto in this narrow regard to set forth the particular transactional data (NDC by NDC, date by date, and price by price) in support of this analysis.

CONCLUSION

For all the foregoing reasons, Mylan's Motion to Dismiss should be denied in its entirety.

⁴ This spread is calculated based on transaction costs of \$0.0682, \$0.0682 and \$0.0405, respectively and does not take into account the AWP discount.

Dated: April 17, 2006.

Respectfully submitted,

**City of New York and all captioned Counties
except Nassau, by**

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